Real-Time Measure of Quantitative Microbial Spore Kill Within a Dry Heat Sterilization Process

The D-value study contained in the CPAC Equipment, Inc. (CPAC) White Paper: "RapidHeat™ High-Velocity Hot Air Sterilization" presents the mechanisms and data needed to create an equation that can mathematically determine incremental amounts of microbial spore kill during a sterilization cycle. This equation, derived from the semi-log plotting of seven D-values from 250°F to 320°F, a range of temperatures used in steam and dry heat sterilization, plays a crucial role in understanding and controlling thermal sterilization processes. The plot demonstrated remarkable linearity and similarity to data obtained by NASA, the high-level research pioneer in the efficacy of the dry heat sterilization process. The linearity shown in CPAC's data, with very little data point deviation, provides a solid basis for using an equation allowing D-values to be established across a broad range of temperatures.

Applying such equation-generated D-values to the average temperature of timed intervals throughout the sterilization process provides a precise 12-Log_{10} measurement of the incremental spore kill during any sterilization cycle. This is a significant step forward in understanding and controlling dry heat sterilization processes. More importantly, if real-time data could be provided by an instrument temperature sensor and integrated into the sterilizer's process controller, the complete sterilization process could be monitored, and the total processing time could be mathematically determined based on actual load conditions. Such a temperature sensor would be, by necessity, small and wireless, allowing it to be located near, on, or within an instrument (medical device). During the sterilization cycle, the sensor(s) would transmit real-time data to the sterilizer's process controller, where algorithmic calculations compute the total time necessary to achieve the required 12-Log_{10} threshold and end the cycle. The placement of the sensor(s) would focus on monitoring the most challenging medical devices in the most challenging location within a load. This approach represents a significant advance in sterilization, moving away from traditional sterilizer-prescribed cycles that have pre-set cycle times regardless of the individual load characteristics.

Currently, thermal sterilization technologies rely on prescriptive cycles that define cycle time at a set chamber temperature. These cycles are derived from meeting a minimum threshold of a 12-Log_{10} microbial spore reduction under defined, maximum instrument load conditions. During the sterilization process, the processing temperature is monitored and controlled by the thermal sensor(s) located in the sterilization chamber remotely from the instrument load. These sensors do not reflect the temperature of the instrument load but only provide evidence of sterilizer performance. Only by locating thermal sensors immediately adjacent to, surface attached, or inserted within an instrument will an accurate measure of instrument temperature be provided, resulting in documented sterilization efficacy of the instrument. Independent temperature sensors are currently available that could monitor temperature adjacent to the instrument. However, they are bulky, rely on internal batteries, require additional insulation for heat protection, and are not designed to interact with the sterilizer's process controller.

Research conducted by CPAC has demonstrated that their RapidHeat™ Pro Series sterilizer cycle temperatures can be precisely and uniformly controlled, monitored, and terminated upon attaining 12-Log_{10} spore reduction. CPAC's patent-pending process can monitor instrument temperatures in real-time through small heat-resistant, wireless, battery-free, remote sensors placed strategically near, attached, or within an instrument. With this capability and the sensor's ability to transmit time and temperature information to the sterilizer's computer for algorithmic processing, the processing cycle for an instrument load can be specifically attained. Each sterilization cycle can be tailored to the actual load configuration and conditions to assure sterilization requirements are achieved, not by assumption or prescriptive cycles but by quantitative measurement.

The system comprises three proprietary integrated components: a Temperature Sensor, a Data Logger, and a Power Distribution Array. These components collect time-temperature measurements and transmit them wirelessly to the sterilizer's computer for heating and process control. The wireless and battery-free temperature sensor is powered by radio frequency (RF) energy emitted by a multidirectional electromagnetic power array in the sterilization chamber.

System Features and Attributes:

<u>Temperature Sensor</u>

- Remote, heat-resistant, and wireless, designed to operate up to 250°C.
- Miniaturized planar design allows placement on or within an instrument.
- Designed to operate singularly or as a multiple series of temperature sensors.
- Operates in a wireless battery-free mode, receiving power via a power harvester.

<u>Data Logger</u>

- Integrates in communication with the controller of the chamber heating system.
- Designed to differentiate radio frequencies and recognize multiple temperature sensors.
- Configured to interact with the electronic controller of a sterilizer's heating system.
- Provides real-time temperature data to the sterilizer's electronic controller.
- Designed to monitor, record, and terminate sterilization at a 12-Log_{10} spore reduction.

<u>Power Distribution Array</u>

- Provides power to the temperature sensor using externally generated RF signals.
- Sensor receiving antenna as a coreless inductor stores charge in an electromagnetic field.
- RF coils configured within the sterilizer chamber ensure optimum RF power for sensors.
- Designed to operate in any thermal sterilization system.

RapidHeat™ Pro Series sterilizers have pioneered the advancements made in high-velocity hot-air sterilization to provide an efficient and cost-effective sterilizing solution for medical instrument sterilization. With the advent of real-time measurement of quantitative microbial reduction in the sterilization process, lower processing times and temperatures can be achieved. The wireless heat-resistant temperature sensor allows sterilization cycles to be tailored to actual load configuration and conditions, ensuring complete load sterility is accomplished, not by assumption or prescriptive cycles but by quantitative documentation. Moreover, the ability of RapidHeat™ Pro Series sterilizers to sterilize at temperatures as low as 270°F confirms that dry-heat thermal sterilization can be further advanced with potential application toward documented sterilization of endoscopes and orthopedic devices.

About the Author

Nelson S. Slavik, Ph.D., is senior vice president of Integrated Medical Technologies, Inc. Responsibilities include research and development of infection control, patient safety, and sterilization technologies. Academically, he holds dual graduate degrees from the University of Illinois at Urbana-Champaign, a Ph.D. in Microbiology and Master of Science in Microbiology/Biochemistry. He served on the faculty of the Department of Health and Safety Studies at the University of Illinois at Urbana- Champaign and as the Biological Safety Director for the campus for over ten years. He has authored over 80 articles on environmental and occupational safety legislation, regulations, and their application and has participated in over 100 healthcare workshops and seminars. He currently holds four patents relating to high-velocity hot air sterilization technology.

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